IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 8025
Guinan *et al.*	Art Unit: 3743
Appl. No.: 09/881,080	Examiner: Odland, Kathryn P.
Filed: June 12, 2001	Atty. Docket: P936US *(1737.2900000)*
For: **Tip Seal Tip Attach**	

Declaration Under 37 C.F.R. § 1.131

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

The undersigned, Terry Guinan, John Connolly, Pat Duane, Donagh O'Shaughnessy, and Michael Bannon, declare and state that,

1. We are the inventors of the above-captioned application, U.S. Appl. No. 09/881,080, filed June 12, 2001.

2. Prior to December 21, 2000, we, the inventors, had completed our invention in the United States, as described and claimed in the subject application, as evidenced by the following.

3. Exhibit A is pages 52-60 of a laboratory notebook of Ronan Rogers in which tests for "B3 Concepts Development Builds" were recorded. In particular, four (4) design concepts were built (at least partially) and tested. Designs "B" and "D" are as described in the claims of the above-referenced application, wherein the guidewire tubular member includes a proximal segment formed of a first material having a first flexibility bonded to a distal segment formed of a second material different from the first material and having a second flexibility, wherein a bond joins the distal end of the balloon to both the proximal and distal segments of the guidewire tubular member.

4. As shown and described on page 53 and FIG. 2.0, Design "B" included a stiff polyethylene ("PE") inner shaft with a PEBAX 6333 co-extruded tip, wherein the PE inner shaft and the tip were bonded end-to-end and to the balloon distal neck.

5. Similarly, as shown and described on page 54 and FIG. 4, Design "D" was similar to Design "B" except that a PEBAX 7233 inner shaft replaced the PE inner shaft. The tip was PEBAX 6333 and the balloon distal neck, PEBAX 7233 inner shaft and PEBAX 6333 tip were bonded together.

6. As shown on page 58, an animal trial was conducted using Design "D" and it worked for its intended purpose.

7. The redacted dates of Exhibit A are prior to December 12, 2000.

As the persons signing below, we hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issue thereupon.

17th August, 2004	Terry Guinan
Date	Terry Guinan
6/8/04	John Connolly
Date	John Connolly
17th Aug 2004	
Date	Pat Duane
16th AUGUST, 2004	
Date	Donagh O'Shaughnessy
17th August, 2004	Michael Bannon
Date	Michael Bannon

TITLE B3 Concept Development Builds Project No. B3

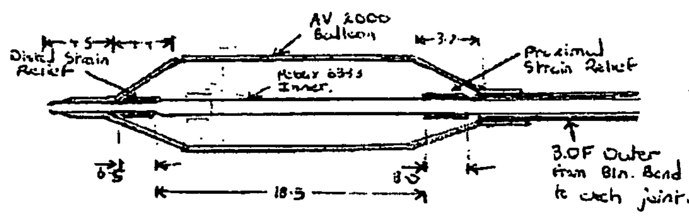
Background

Four major Stent delivery designs were devised with the emphasis placed on producing smooth trackability. The general guide line was to reduce ~~??~~ stiffness transitions along the distal section of the system, specifically the areas of localised "low" stiffness immediately proximal and distal to the stent (see P30). These particular areas may result in potential hinge points.

~~Des~~ Four designs were fabricated, ie A, B, C + D. Designs A + D were used in an acute animal trial for the BeStent 3 Coronary Stent System on the 3rd July 2000 and designs A, B + C were benchtested using the 90° wire track test to correlate with the animal trial results.

The four designs were a follows:-

Design A.



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RR

Fig 1 Design A

Design A (see RT B2 0006095) uses the AV 2000 balloon and the more flexible Pebax 6333 inner

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It has a 3.0 F outer from the balloon bond to the exchange joint and a distal and proximal strain relief ~~from~~ RR 7/6/00 welded to the inner under the proximal and distal balloon cones (see fig 1). The distal strain relief is a 3.5 mm long section of AV100 distal balloon neck, while the proximal strain relief is a section of Calypso Exact proximal balloon neck.

Design B

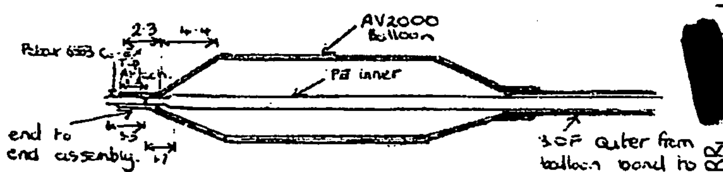

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Fig2.0 Design B

Design B (see RT B2 0006096) has the same balloon and outer as Design A (this design feature is common to all the designs). It has a stiff PE inner that has a Pebax 6333 Co-Ex Tip attach under the distal balloon neck. The tip and inner are assembled end to end and welded together, and to the balloon, RR 6/7/00 ~~and~~ during tip seal.

Design C

Design C ~~has~~ RR 6/7/00 is similar to Design B ~~but~~ RR 6/7/00 except the Pebax 6333 is joined to the PE inner midway between the proximal and distal balloon cones.

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as in Fig 3.0 in the centre of the balloon. The joint between the two inners is created by necking the Pebax and Flaring the PE (see RT B2 0806 112) similar to the OTW SA

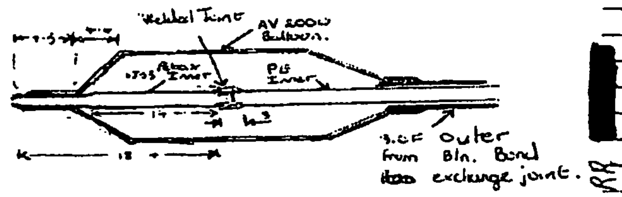

Fig 3.0 Design C.

tip attach process. The joint is welded together to form a 3mm long joint.

Design D

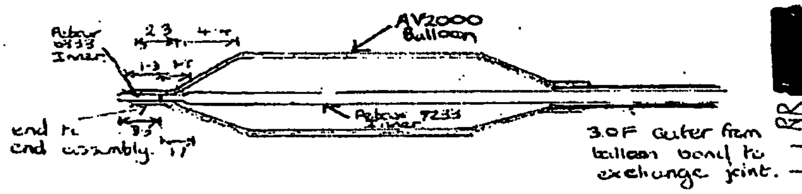

Fig. 4.0 Design D.

Design D is similar to Design B except instead of the PE inner ~~from the~~ there is a Pebax 7233 inner extending from the distal balloon neck proximally. This was neccessary as it proved impossible

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to laminate the exchange joints on Designs B + C due to the presence of the PE. Therefore designs B + C ~~there~~ RR 10/7/00 only contain the distal sections. Designs A + D are complete builds.

Results

Design A

Animal Trial:

Trackability + Pushability + Pull back evaluation — rated better than all the prototypes or competitors used in the trial for track and pull back into the guide, with equivalent pushability

Side Branch Access evaluation — the best of all the systems tried — accessed the side branch quite easily

Bench Test.

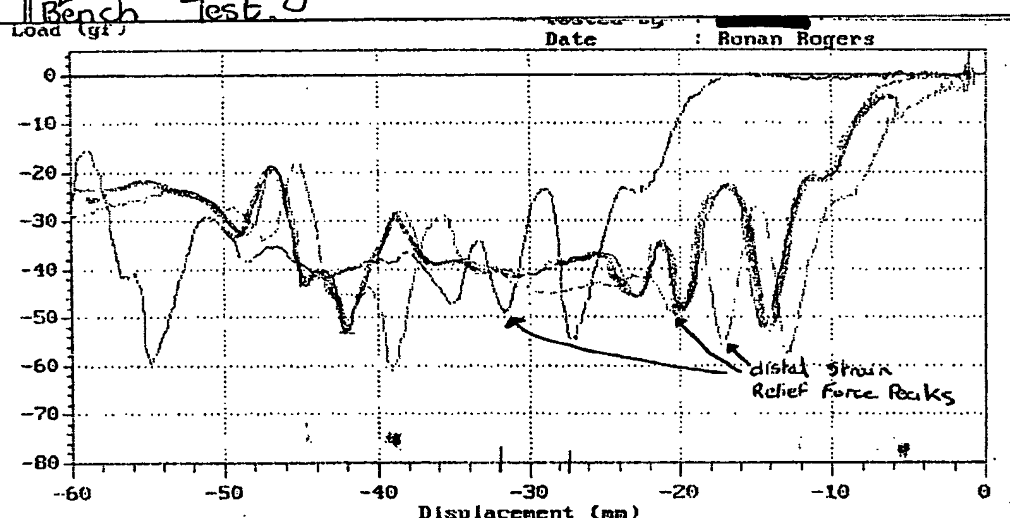

Fig. 50 Design A Wire Track Results.

Ronan Rogers

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From Fig.5 it can be seen the distal strain relief is very prominent and has a very definite force peak. The proximal strain is not very obvious, but there is some evidence to suggest the trough between the proximal end of the stent and the balloon bond has been shortened (see P.28). See Table 1 for tabulated results.

Design B

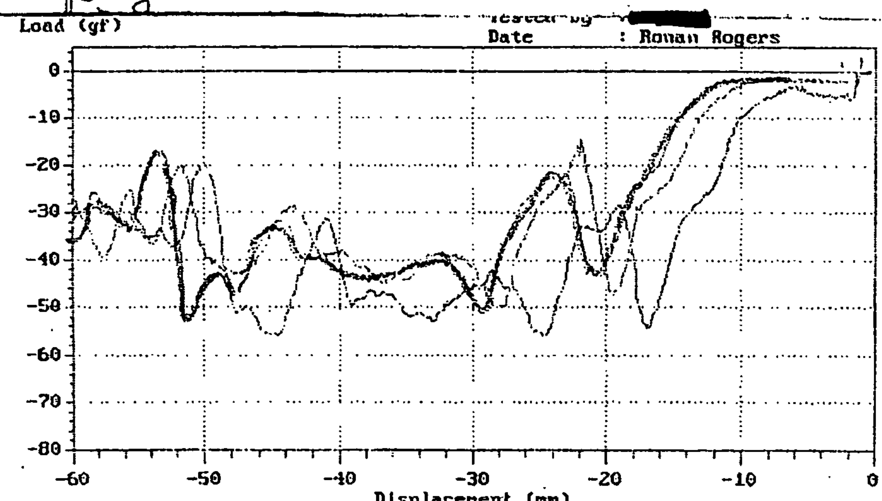

Fig. 6.0 Design B Wire Track Results.

[redacted] RR

Animal Trial :— N/A.

Bench Test.

Design B has a slighty smoother track profile, especially towards the ~~distal~~ proximal

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end. This is due to the stiff PE inner, but the distal trough is very evident, while a kinking effect in the PE was noticed proximal to balloon bond, during testing.

Design C

Animal Trial – N/A

Bench Test

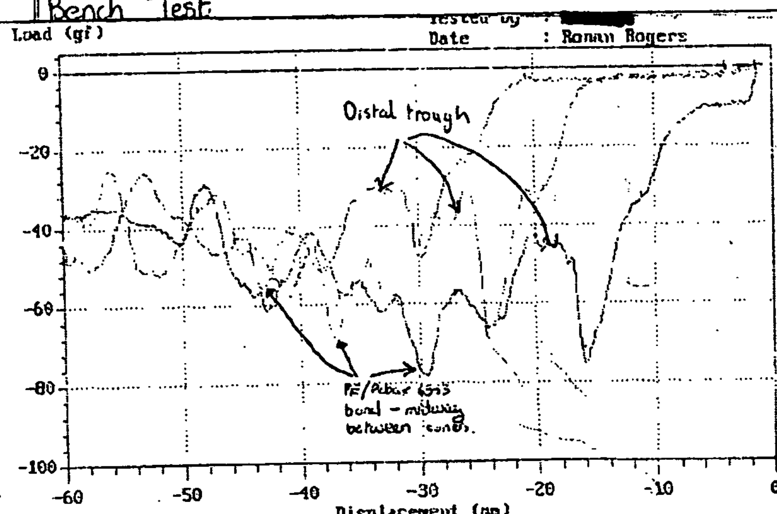

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Fig. 7.0 Design C Wire Track Results.

From Fig 7.0 the two most striking features are the large width of the distal trough and the distinctive peak caused by the bond between the two inners midway

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between the balloon cones. This obviously highlights the stiffnesses that can be achieved by welding materials on the inner and how the PE does not produce the required stiffness to minimise/affect the distal trough

Design D

Animal Trial — system trackability + pushability were rated equivalent to the competitor but there was resistance on pullback into the guide

Bench Test — N/A

Tetra + Velocity
~~Bench Test~~ RR

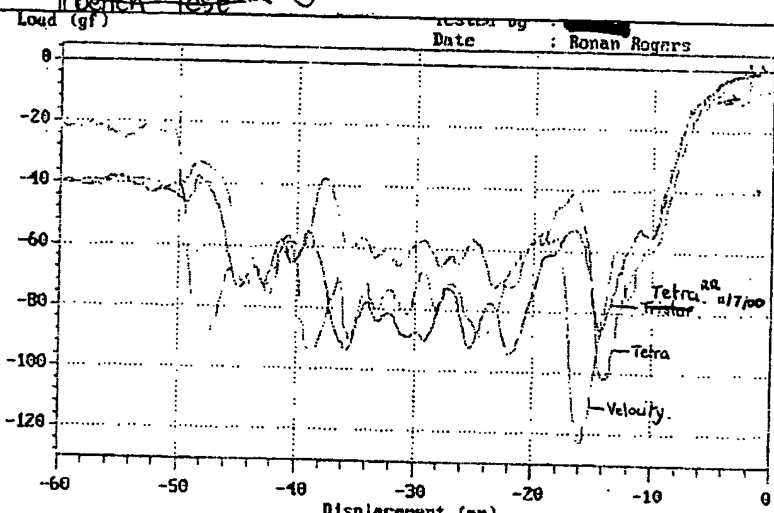

Fig 8.0 Tetra + Velocity Wire Track Results.

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Animal Trial

Tetra – trackability worse than prototypes – more resistance on pullback into guide. It had equivalent side branch access.

Velocity – much worse than all previous prototypes – more resistance on pullback into the guide.

Bench Test

Fig 9.0 shows that Tetra and Velocity have a much worse track than any of the previous prototypes with Velocity being the worst, especially at the welds.

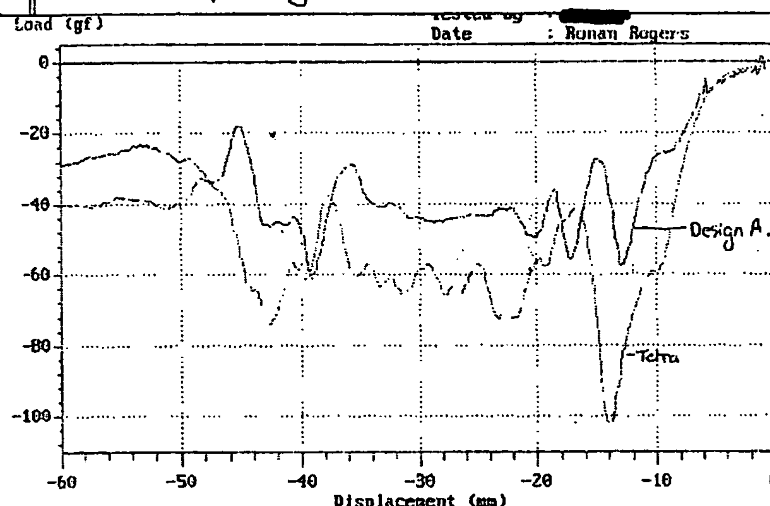

Fig 9.0 Tetra vs Design A

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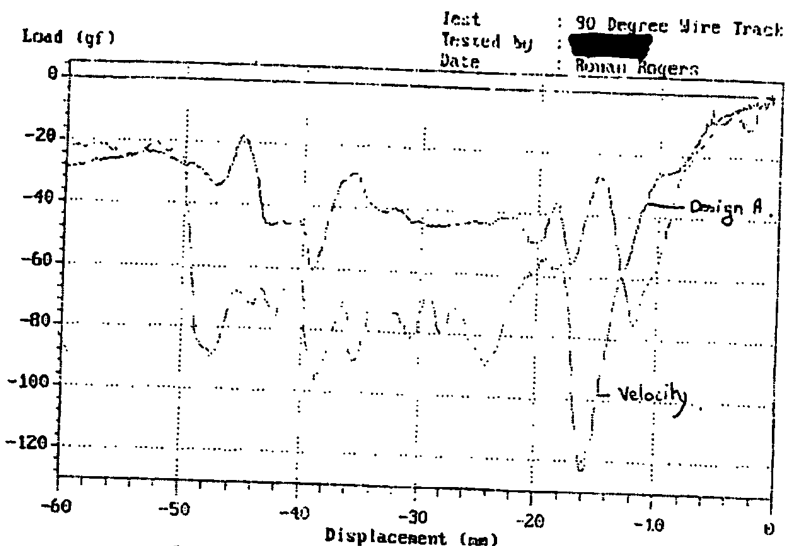

Fig 10.0 Velocity vs Design A. RR [redacted]

Conclusions

The following are some of the conclusions arising from the bench testing and animal trial – both results concurred well with each other

- B2 in its current form performs considerably better in track than Tetra & Velocity (see
- Of the three designs Design A performed the best – the distal strain relief was evident
- The PE inner on Design B+C had some effect on reducing the proximal hinge.
- The tip attach on design B was not noticable.

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